

## **Package leaflet: Information for the user**

### **Monovo 1 mg/g cutaneous emulsion**

mometasone furoate

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Monovo is and what it is used for
2. What you need to know before you use Monovo
3. How to use Monovo
4. Possible side effects
5. How to store Monovo
6. Contents of the pack and other information

#### **1. What Monovo is and what it is used for**

Monovo contains the active substance mometasone furoate, which belongs to a group of medicines called topical corticosteroids (or steroids).

Topical corticosteroids can be divided into four degrees of strength or potency: mild, moderate, potent and very potent. The active ingredient of Monovo is classified as a “potent corticosteroid”.

In adults and children, aged 6 years and over, Monovo is used to reduce symptoms caused by certain inflammatory skin problems such as psoriasis (excluding widespread plaque psoriasis) and some types of dermatitis. In addition, Monovo is used to reduce symptoms caused by certain inflammatory and itching skin problems of the scalp such as scalp psoriasis.

#### **2. What you need to know before you use Monovo**

##### **Do not use Monovo**

- if you, or your child are allergic to mometasone furoate, other corticosteroids or to any of the other ingredients of this medicine (listed in section 6)
- on any other skin problems as it could make them worse especially:
  - rosacea (a skin condition affecting the face)
  - acne
  - skin atrophy (thinning of the skin)
  - dermatitis around the mouth
  - itching around the anus and genitals
  - nappy rash
  - bacterial infections such as impetigo (school sores, skin infection), pyoderma (appears as pus-filled lesions, skin infection), tuberculosis, syphilis (a sexually transmitted disease)
  - viral infections such as cold sores, shingles, chickenpox (varicella), common warts, genital and water warts
  - parasitical skin infections such as scabies

- fungal infections such as athlete's foot (red, itchy, flaky skin on the feet), or thrush (an infection affecting the vagina that can cause discharge and itching)
- wounds and ulcerated skin
- if you have a reaction to a vaccination (e.g. for flu).

### **Warnings and precautions**

- Monovo should not be put on the eyelids.
- Take care not to get Monovo in the eye. However, if this should occur rinse thoroughly with clean water. If eye irritation remains please see your doctor.
- If irritation or sensitisation develops with the use of Monovo, discontinue treatment and tell your doctor immediately.
- **Do not** apply a bandage or dressing to the area being treated with Monovo, unless specially directed to do so by your doctor.
- When this medication is used on psoriasis, it may make the conditions worse (e.g. a pustular form of the disease may occur). You should let your doctor review your progress at regular intervals, as such treatment needs careful supervision.
- **Do not** use Monovo on your face without close supervision by your doctor.
- Contact your doctor if you experience blurred vision or other visual disturbances.

### **Other medicines and Monovo**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

During pregnancy or while you are breast-feeding, treatment with Monovo should only be started following instructions from your doctor.

If your doctor does prescribe Monovo to you during pregnancy or while you are breast-feeding, you should avoid using large doses and the use should be limited to a short period.

**Do not** apply Monovo to the breast area whilst breast-feeding.

### **Driving and using machines**

Mometasone furoate is not known to affect your ability to drive and use machines.

### **Monovo contains propylene glycol caprylate**

Monovo contains propylene glycol caprylate which may cause skin irritation.

## **3. How to use Monovo**

Monovo is for use on the skin (cutaneous use).

This medicinal product is for external use only.

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor should review your treatment at regular intervals, especially when Monovo is applied on the face, as potent topical corticosteroids generally should not be applied to the face without close monitoring by the physician.

**If not indicated otherwise by your doctor**, turn the bottle upside down, gently squeeze the bottle and count 10 to 12 drops in the palm of your hand. This amount is enough to cover an area twice the size of an adult hand.

For smaller areas, use a smaller amount.  
Monovo should be applied to the affected skin area once daily.  
Massage gently and thoroughly until the medicine disappears.

**Adults, including the elderly:**

You **should not** use Monovo on large areas of the body (over 20 % of body surface area) or for a long time (for example every day for over three weeks).

Unless directed by your doctor, **do not** apply a bandage or dressing to the area being treated. This will increase absorption of the preparation and increase possible side effects.

**Children (6 years of age and over):**

**Do not** use Monovo for children over 6 years of age on any part of their body without close supervision of the doctor.

**Do not** apply Monovo to more than 10 % of the child's body surface area.

**Do not** use in skin folds or under airtight dressings.

**Do not** use for more than 3 weeks.

**Children (under 6 years of age):**

Monovo is **not** recommended to be used in children under 6 years of age.

**If you used more Monovo than you should**

If you (or somebody else) accidentally swallow Monovo, it should not produce any undesirable effects. However, if you are worried, you should see your doctor or pharmacist.

If you use Monovo more often than you should, or on large areas of the body, it can affect some of your hormones. In children, this may affect their growth and development.

If you have not followed the dosage instructions or your doctor's advice and have used Monovo too frequently and/or for a long time, you should tell your doctor or pharmacist.

**If you forget to use Monovo**

If you forget to apply Monovo at the scheduled time, do it as soon as you remember and then carry on as before.

**Do not** apply twice as much or use twice in one day to make up for a missed application.

**If you stop using Monovo**

**Do not** stop treatment suddenly if you have used it for a long time since this may be harmful. Treatment should be stopped gradually, as advised by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If your symptoms do not begin to improve after using this preparation as instructed by your doctor or if they get worse, check with your doctor.

**Side effects that have been reported with the use of topical corticosteroids include:**

**Common: may affect up to 1 in 10 people**

- mild to moderate burning sensations at the application site
- tingling/stinging
- itching

- bacterial infections
- abnormal sensations on the skin
- skin boils
- thinning of the skin

**Uncommon: may affect up to 1 in 100 people**

- irregular skin marks or stripes
- skin irritation
- increased hair growth
- decrease of skin colour
- dermatitis around the mouth
- softening and whitening of the skin
- allergic contact dermatitis
- pus-filled blisters on facial skin
- acne-like reactions
- purple or dark blue discoloration of the skin
- heat rash
- dryness
- sensitisation
- inflammation of skin follicles
- secondary infection

**Very rare: may affect up to 1 in 10,000 people**

- dilated blood vessels on the skin or spider veins.

**Not known: frequency cannot be estimated from the available data**

- Blurred vision.

Increased usage, treatment of large areas of skin, long term use and use under a dressing may increase the risk of side effects.

Corticosteroids may affect the normal production of steroids in the body. This is more likely to happen if high doses are being used over a long period of time.

Allergic (hypersensitivity) reactions have been reported in connection with propylene glycol and frequencies are unknown.

**Additional side effects in children**

Children in particular, treated with corticosteroid preparations can absorb the steroid through the skin and this can lead to a disorder called Cushing's syndrome which includes many symptoms, such as a fat, round face and weakness. Children on long term treatment may grow more slowly than others. Your doctor will help prevent this happening by prescribing the lowest dose of steroid at which your symptoms are well-controlled.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie) , e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Monovo**

Keep this medicine out of the sight and reach of children.

Do not use Monovo after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not freeze.

Discard the opened bottle with any remaining cutaneous emulsion after 3 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What Monovo contains

- The active substance is mometasone furoate.

Each gram of Monovo contains 1 mg of mometasone furoate (0.1 % w/w mometasone furoate).

Each drop of Monovo contains 0.05 mg of mometasone furoate.

- The other ingredients are:

Purified water, liquid paraffin, hexylene glycol, octyldodecanol, medium-chain triglycerides, macrogol stearyl ether (21), macrogol stearyl ether (2), diisopropyl adipate, propylene glycol caprylate, hard paraffin, phenoxyethanol, citric acid, sodium citrate, xanthan gum.

### What Monovo looks like and contents of the pack

Monovo is a white cutaneous emulsion. The cutaneous emulsion is filled in polyethylene bottles fitted with a blue or white polyethylene screw cap with a nozzle in a cardboard carton.

Pack sizes: 20 g, 30 g, 50 g, 60g and 100 g emulsion.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

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Germany  
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**This medicinal product is authorised in the Member States of the EEA under the following names:**

Country	Trade names
Austria	Monovo 1 mg/g Emulsion zur Anwendung auf der Haut
Denmark	Monovo 1 mg/g kutan emulsion
Finland	Monovo 1 mg/g Emulsio iholle
Germany	Monovo 1 mg/g Emulsion zur Anwendung auf der Haut
Ireland	Monovo 1 mg/g cutaneous emulsion
Italy	Mundoson Fluido 1 mg/g Emulsione cutanea
Luxembourg	Monovo 1 mg/g Emulsion
Norway	Monovo
Poland	Ivoxel
Portugal	Ivoxel 1 mg/g Emulsão cutânea
Sweden	Monovo

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